

506, 507, or 512 of the act or section 351 of the Public Health Service Act.

§ 207.35 Notification of registrant; drug establishment registration number and drug listing number.

(a) FDA will provide to the registrant a validated copy of Form FDA-2656 (Registration of Drug Establishment) as evidence of registration. This validated copy will be sent to the mailing address shown on the form. FDA will assign a permanent registration number to each drug establishment registered in accordance with these regulations.

(b) Using the National Drug Code (NDC) numbering system, FDA assigns a drug listing number to each drug or class of drugs listed as follows:

(1) If a drug is already listed in the National Drug Code System or in the National Health Related Items Code System, the number is the same as that assigned under those codes. FDA adds a lead zero to the first three characters of the code, which identifies the manufacturer or distributor, to expand the "Labeler Code" segment to four characters. The National Drug Code, Product Code, and Package Code configurations used to describe these drugs, or any drugs added to the product line, remain the same, i.e., a four-character Product Code and a two-character Package Code. A manufacturer or distributor may either retain alphanumeric characters that are already used in the Product Code and Package Code segments of the National Drug Code or convert these alphanumeric characters to all numeric digits. The manufacturer or distributor shall inform FDA of a decision to convert the alphanumeric characters to all numeric digits.

(2) If a registered establishment or distributor has not previously participated in the National Drug Code System or in the National Health Related Items Code System, FDA uses the National Drug Code numbering system in assigning a number, as follows (only numerals are used):

(i) The first 5 numeric characters of the 10-character code identify the manufacturer or distributor and are known as the Labeler Code. FDA will expand the Labeler Code from five to six nu-

meric characters when the available five-character code combinations are exhausted. FDA will assign Labeler Code numbers and provide them to the registrant along with the validated copy of Form FDA-2656. Any registered firm that does not have an assigned Labeler Code will be assigned one when registration and listing information are submitted.

(ii) The last 5 numeric characters of the 10-character code identify the drug and the trade package size and type. The segment that identifies the drug formulation is known as the Product Code and the segment that identifies the trade package size and type is known as the Package Code. The manufacturer or distributor will assign the Product Code and the Package Code before drug listing and include these codes in Form FDA-2657 (Drug Product Listing). The manufacturer or distributor may use either of two methods in assigning the Product and Package Codes: a 3-2 Product-Package Code configuration (e.g., 542-12) or a 4-1 Product-Package Code configuration (e.g., 5421-2). A manufacturer or distributor with a given Labeler Code shall use only one such Product-Package Code configuration and shall use this same configuration in assigning the Product-Package Codes for all drugs included in the drug listing. The manufacturer or distributor shall report to FDA the Product-Package Code configuration used in assigning these codes.

(iii) If the drug formulation is a Type A medicated article intended for use in the manufacture of an animal feed, FDA assigns a separate Product Code only for each variation of level of active drug ingredient.

(3) FDA requests but does not require that the NDC number appear on all drug labels and in other drug labeling, including the label of any prescription drug container furnished to a consumer. If the NDC number is shown on a drug label, it shall be placed as follows:

(i) The NDC number shall appear prominently in the top third of the principal display panel of the label on the immediate container and of any outside container or wrapper. Instead of appearing in the top third of the label, the NDC number may appear as

part of and contiguous to any bar-code symbol for any drug product if two conditions are met. First, the symbol appears prominently on the immediate container and on any outside container or wrapper and in a conspicuous location; this condition is not satisfied by the appearance of the symbol only on the natural bottom of a container or wrapper. Second, the bar-code symbol is compatible with the NDC, i.e., the symbol provides a format capable of encoding the numeric characters of an NDC Number. The term *principal display panel*, as used in this paragraph, means that part of a label most likely to be displayed, presented, shown, or examined under customary conditions of display to the consumer (for over-the-counter drug products) or to the dispenser (for prescription drug products).

(ii) The NDC number shall be preceded by the prefix "NDC" or "N" when it is used on a label or in labeling. The prefix used for a drug product shall be used consistently on the label of the immediate container, outside container, or wrapper, if any, and on other labeling for that drug product.

(iii) The Product-Package Code configuration shall be indicated and the segments of the number shall be separated by a dash, e.g., NDC 15643-542-12 or N 15643-542-12.

(iv) All 10 characters shall appear and the leading zeros in any segment of the NDC number shall be shown, except that leading zeros may be omitted from any segment of the NDC number when the NDC number is used for product identification by direct imprinting on dosage forms or in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear both required and optional labeling information.

(v) The placing of the assigned NDC number on a label or in other labeling does not require the submission of a supplemental new drug application, supplemental new animal drug application, or supplemental antibiotic application.

(4)(i) If any change occurs in those product characteristics that clearly distinguish one drug product version from another, the registrant shall assign a new NDC number to the new

product version and submit that information to FDA. Such a change includes, but is not limited to, a change in active ingredient(s); strength or concentration of active ingredient(s); dosage form; route of administration, if it also includes a change in product formulation; product name; and a change in marketing status from prescription to over-the-counter or over-the-counter to prescription. If, by notice in the FEDERAL REGISTER, FDA requires a change in drug product characteristics and determines the change will require assignment of a new product code to the reformulated product, FDA will announce its determination in the FEDERAL REGISTER publication that requires the change, setting forth its reasoning and justification for its determination. If a change only in the trade package is involved, the registrant may revise the trade package code without the assignment of a new product code segment, but shall inform FDA of the new code for the trade package and the characteristics of the new trade package.

(ii) When a registrant has discontinued a drug product, its product code may be reassigned to another drug product 5 years after the expiration date of the discontinued product, or, if there is no expiration date, 5 years after the last shipment of the discontinued product into commercial distribution. Reuse of product codes may occur, under the specified conditions, regardless of the NDC, Product Code, and Package Code configuration used.

(c) Although registration and drug listing are required to engage in the drug activities described in § 207.20, validation of registration and the assignment of a drug listing number do not, in themselves, establish that the holder of the registration is legally qualified to deal in such drugs.

[45 FR 38043, June 6, 1980, as amended at 48 FR 54007, Nov. 30, 1983; 52 FR 2682, Jan. 26, 1987; 55 FR 11577, Mar. 29, 1990]

§207.37 Inspection of registrations and drug listings.

(a) A copy of the Form FDA-2656 (Registration of Drug Establishment) filed by the registrant will be available